

### **REMARKS**

Claims 1-4 and 23-28 are currently pending to which the Examiner provides two obviousness rejections.

**I. Rejections Under Obviousness**

- A. Claims 1-4 and 23-24 are rejected under 35 USC § 103(a) as allegedly being unpatentable over United States Patent No. 6,726,923 To Iyer et al., in view of United States Patent No. 6,068,654 To Berg et al.
- B. Claims 25-28 are rejected under 35 USC § 103(a) as allegedly being unpatentable over United States Patent No. 6,726,923 To Iyer et al., in view of United States Patent No. 3,902,497 To Casey.

**I. The Claims Are Not *Prima Facie* Obvious**

**A. Claims 1-4 & 23-24 Are Not Obvious Under Iyer et al. and Berg et al.**

**1. Berg et al. Is Not A Drug Delivery Device**

In the present case, Berg et al. teach that one piece of Connector 10 (i.e., the tubular anchor structure) is based upon stent technology:

... tubular anchor structure 30 may be a modified metal tube, formed from expandable metal - ... this type of structure is frequently found in stents used to prevent collapses of tubular body structures, and tubular anchor structure 30 could be a converted stent, possibly with some modifications.

*Berg et al., col 5 ln 45-53.* Iyer et al. explicitly teaches away from Berg et al. by pointing out that stent technology has a high risk of failure:

Stents are either “balloon-expandable” or “self-expanding” and when deployed endovascularly, abut against the inner vessel wall. Whether or not a stent is placed, this form of treatment has a high risk of failure ...

*Iyer et al. col 3 ln 1-4.* Consequently, one having ordinary skill in the art would not read Iyer et al. and consider using Berg’s risky technology. Further, at no point does Berg et

al. teach that the contemplated materials can provide drug elution matrix as required by Iyer et al. In contrast, Berg et al. teaches a permanent and structurally dependable device:

An advantageous characteristic of the above described framework is that it is extremely elastic and resilient. Thus it can be radically deformed (e.g., during installation and before tubular anchor structure 50 is expanded), and it thereafter returns to its original shape with our any damage or memory that it was deformed.

*Berg et al.*, col 6 ln 28-33. In contrast, Iyer et al. teaches that the drug delivery device must biodegrade to provide controlled drug elution:

A device of this invention may employ a ... biodegradable resorbable matrix material ... An important factor in the selection of a particular matrix material is the porosity and ... a controllable rate of biodegradation. The characteristics of the matrix material is important because the material creates a delivery depot or reservoir and control the kinetics of agent delivery.

*Iyer et al.*, col 8 ln 37-49 [emphasis added]. Therefore, required physical materials between Iyer et al. and Berg et al. are inherently incompatible because Iyer's biodegradable drug-eluting matrix cannot provide the required physical support for an end-to-side anastomosis as described by Berg et al. See, "Penman Declaration" *para* 6.

References having teachings that, when combined, result in inoperable embodiments of the disclosed technology within the references cannot be used to support an obviousness rejection. It is well settled patent law that this situation results in a 'teaching away':

If references taken in combination would produce a 'seemingly inoperative device', we have held that such references teach away from the combination and thus cannot serve as predicates for the *prima facie* case of obviousness.

*In re Spinnoble*, 405 F.2d 578, 587 (1969)(references teach away from combination if combination produces seemingly inoperative device); see also *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir 1984)(inoperable combination teaches away).

**2. Neither Iyer et al. Nor Berg et al. Teach A Surgical Wrap With An Annular Shape And Radial Edge**

The Examiner openly admits that:

Iyer et al. do not teach expressly a matrix with annular shape and radial edge.

*Office Action pg 3 ¶ 5.* Further, the Examiner only offers Berg et al. for:

... T-shaped Joint location of vascular vessel is normally in the shape of a circle, and the connector of the joint is in the shape of annular. See, the figures.

*Office Action pg 3 ¶ 5.* The United States Supreme Court has held that an obviousness rejection must be supported by substantive argument and evidence:

Often, it will be necessary ... to look to interrelated teachings of multiple patents ... in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See, *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

*KSR v. Teleflex, Slip Op No. 04-1350 (April 30, 2007).* The Examiner has provided no articulated reasoning but merely says 'look at the figure' without showing that Berg et al. had any explicit or implicit intent to describe an annular sheet of material with a radial edge. The Examiner is engaged in speculation and is improperly acting as one skilled in the art. The Examiner is reminded that - under the law - an Examiner is NOT one skilled in the art; mere opinion of the Examiner on what one skilled in the art might believe does not count. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art.").

Without evidence generated by one having ordinary skill in the art that by viewing Berg's figures would result in the Applicants' claimed embodiment, the Examiner has failed to present a *prima facie* case of obviousness based upon Iyer et al. and Berg et al. Berg et al. describes a device designed to hold and seal together an end-to-side anastomosis:

When tubular anchor structure 30 firmly engages retention loops 26, lip 28 of tubular band section 20 preferably is drawn to aperture 13 in side wall 14, and preferably forms a hemodynamic seal between tubular band section 20 and side wall 14.

*Berg et al. col 5 ln 13-17 [emphasis added].* In contrast, Iyer et al. provides a drug delivery platform applied to an anastomosis after the vessels have been structurally stabilized:

The composite device or sleeve is then suitably trimmed so that it can be applied over the desired site(s): artery, vein, graft, anastomotic site etc. ...

*Iyer et al. col 11 ln 1-13.* Indeed, 'The Penman Declaration' provides evidence that Iyer et al. does not teach devices or methods by which an anastomosis may be sealed. *See, para 7.*

Moreover, Berg et al. teaches only a device that is at least partially intraluminally inserted into a vessel:

Connector 10 preferably includes a tubular band section 20 adapted to be received in or around an end of a tubular graft 12.

*Berg et al. col 2 ln 36-42.* Consequently, Berg et al. is not relevant to the Applicants' claimed embodiment that recites a surgical wrap intended for the exterior surface of body tissues.

The Applicants, therefore, respectfully request that the Examiner withdraw this rejection.

**B. Claims 25-28 Are Not Obvious Over Iyer et al., Berg et al. And Casey.**

The Applicants rely upon the above argument showing that Iyer et al. and Berg et al. are insufficient to make obvious a sheet of material having an annular shape and radial edge. Casey does not fulfill these deficiencies. As discussed in 'The Penman Declaration', Casey has no relevancy to surgically implanted drug delivery devices. *See para 9.* In particular, Casey teaches a device that absorbs solutions and/or compounds, not devices that release solutions and/or compounds:

It may be used in procedures in which the foam sponge is left in the wound ... to absorb blood, serum or other liquids ...


*Casey, col 2 ln 60-63.* Again the Examiner has failed to create a *prima facie* case of obviousness.

The Applicants respectfully request that the Examiner withdraw the present rejection.

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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